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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,793	02/12/2001	Seth A. Foerster	A1714	6962

33197 7590 12/16/2003

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EXAMINER

ODLAND, KATHRYN P

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/781,793

Applicant(s)

FOERSTER, SETH A.

Examiner

Kathryn Odland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 8, 10-25 and 27-38 is/are rejected.
- 7) ☒ Claim(s) 5, 9, 26 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 5, 7, 8 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: element 90. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: the Brief Description of the Drawings, on page 12, references Figure 11. It appears that there is not a Figure 11 rather figures 11A and 11B.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 10, 15, 16, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Goble et al. in US Patent No. 5,702,397.

Regarding claim 1, Goble et al. disclose a knotless suture anchor apparatus for anchoring a length of suture with respect to a body cavity having an anchor body (136) having an anchoring structure (such as 137) for fixing the anchor body (136) within a

body cavity, the anchor body having a proximal end, a distal end, and a lumen (140 with 143, 144) opening at the proximal end, the anchor body further including a suture pulley (141) fixed with respect to the anchor body such that a length of suture may be introduced into the lumen from the proximal end, looped around the pulley, and passed out of the lumen through the proximal end; and a suture locking plug (145) movable within the lumen from a first position to a second position, as recited in column 2, lines 50-55, column 11, lines 60-67, column 12, and seen in figure 23.

Regarding claim 2, Goble et al. disclose that as applied to claim 1, as well as, a suture locking plug (145) and lumen that cooperate such that the suture locking plug (145) does not interfere with axial movement of the length of suture in the first position and interferes with axial movement of the length of suture in the second position, as recited in column 11, lines 60-67, column 12, and seen in figure 23 (when the plug (145) is not engaged the suture can pass through until locked by plug (145)).

Regarding claim 3, Goble et al. disclose that as applied to claim 2, as well as, a suture locking plug (145) that interferes with axial movement of the length of suture in the second position by compressing the length of suture against the anchor body, as recited in column 11, lines 60-67, column 12, and seen in figure 23.

Regarding claim 4, Goble et al. disclose that as applied to claim 1, as well as, an anchor body that is generally tubular and the lumen opens at the distal end as well as at the proximal end, as recited in column 11, lines 60-67, column 12, and seen in figure 23.

Regarding claim 10, Goble et al. disclose that as applied to claim 1, as well as, a fixed suture pulley is that formed in a sidewall of the lumen, as recited in column 11, lines 60-67, column 12, and seen in figure 23.

Regarding claim 15, Goble et al. disclose a knotless suture anchor apparatus for anchoring a length of suture (27) with respect thereto, having an anchor body (136) with a proximal end, a distal end, and a lumen (140, 143, 144) opening at the proximal end, the anchor body further including a suture pulley (141) fixed with respect to the anchor body such that a length of suture may be introduced into lumen from the proximal end, looped around the pulley, and passed out of the lumen through the proximal end; and a suture locking plug (145) movable within the lumen from a first position which does not interfere with axial movement of the length of suture to a second position that compresses the length of suture against the anchor body and interferes with axial movement of the length of suture, as recited in column 11, lines 60-67, column 12, and seen in figure 23.

Regarding claim 16, Goble et al. disclose that as applied to claim 15, as well as, an anchor body that is generally tubular and the lumen opens at the distal end as well as at

the proximal end, as recited in column 11, lines 60-67, column 12, and seen in figure 23.

Regarding claim 19, Goble et al. disclose that as applied to claim 15, as well as, a fixed suture pulley (141) that is formed in a sidewall of the lumen, as recited in column 11, lines 60-67, column 12, and seen in figure 23.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 6-8, 11-14, 18, 20-25, and 27-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goble et al. in US Patent No. 5,702,397.

Regarding claim 6, Goble et al. disclose that as applied to claim 4. However, Goble et al. do not explicitly recite a suture locking plug that has a shaft axially displaceable within the lumen. On the other hand, figure 15 of Goble et al. teach a suture locking plug that has a shaft axially displaceable within the lumen. Thus, it would be obvious to modify the invention of figure 23 to include the teaching of a suture locking plug that has a shaft axially displaceable within the lumen for the purpose of precise control of suture tension.

Regarding claim 7, Goble et al. as modified disclose that as applied to claim 6.

However, Goble et al. do not explicitly recite a suture locking plug further includes a distal stop larger in cross-sectional dimension than the lumen diameter that interferes with the anchor body and limits proximal movement of the shaft with respect thereto.

On the other hand, figure 15 of Goble et al. show a suture locking plug further includes a distal stop (via ridges 56 and 54) larger in cross-sectional dimension than the lumen diameter that interferes with the anchor body and limits proximal movement of the shaft with respect thereto. Thus, it would be obvious to further modify the invention shown in figure 23 to include a suture locking plug further including a distal stop larger in cross-sectional dimension than the lumen diameter that interferes with the anchor body and limits proximal movement of the shaft with respect thereto, for the purpose of more precise control of suture tension, as discussed in column 2, lines 50-55.

Regarding claims 8, 18, and 25, Goble et al. as modified disclose that as applied to claims 7, 17, and 24. However, Goble et al. do not explicitly recite an actuation rod removably attached to the proximal end of the shaft and projecting out of the proximal end of the anchor body, the actuation rod usable to displace the shaft axially within the lumen in figure 23. However, Goble et al. to teach actuation rods (such as 60, etc.) removably attached to the proximal end of the shaft and projecting out of the proximal end of the anchor body. Therefore, it would be obvious to one with ordinary skill in the art to further modify the invention as shown in figure 23 to include actuation rods for the purpose of displacing the shaft axially within the lumen.

Regarding claims 11 and 20, Goble et al. disclose that as applied to claims 10 and 19, as well as, an anchor body (136) that is a tubular body defining the lumen (140, 143, 144) therein which is cylindrical. However, a fixed suture pulley that is disposed at a distal end of the tubular body is not explicitly recited. On the other hand, is within the scope of the invention and would be obvious to one with ordinary skill in the art to modify the invention to have the suture pulley (141) at the distal end of the tubular body for the purpose of longer suture retention.

Regarding claims 12 and 21, Goble et al. as modified disclose that as applied to claims 11 and 20, as well as, a lumen that opens at the distal end of the tubular body as well as at the proximal end, and wherein the pulley (141) is a rod (142) at the open distal end transverse to the lumen axis, as recited in column 11, lines 60-67, column 12, and seen in figure 23.

Regarding claims 13 and 22, Goble et al. as modified disclose that as applied to claims 12 and 21, as well as, a rod (142) that rotates with respect to the anchor body, as recited in column 11, lines 60-67, column 12, and seen in figure 23.

Regarding claims 14 and 23, Goble et al. as modified disclose that as applied to claims 11 and 20. Further, a pulley that is a bridge between two spaced apertures (such as 143, 144) at the distal end of the tubular body is within the scope of the invention, for

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although the pulley is not exactly at the distal end of the tubular body, it would be obvious to one with ordinary skill in the art to modify the invention to have the pulley at the distal end for the purpose longer suture retention.

Regarding claim 17, see that stated above with regard to the rejection of claims 6 and 7.

Regarding claim 24, Goble et al. disclose a knotless suture anchor apparatus for anchoring a length of suture with respect to a body cavity, having an anchor body (136) having an anchoring structure (such as 137) for fixing the anchor body within a body cavity, the anchor body having a proximal end, a distal end, and a lumen (140, 143, 144) opening at both the proximal and distal ends, the lumen having a diameter that permits a length of suture to be passed therethrough; and a suture locking plug (145), wherein the suture locking plug is movable within the lumen from a first position which does not interfere with axial movement of the length of suture to a second position that interferes with axial movement of the length of suture, and wherein a stop is provided that positively interferes with proximal movement of the suture locking plug with respect to the anchor body, as recited in column 11, lines 60-67, column 12, and seen in figure 23. However, Goble et al. do not recite a suture locking plug having a shaft axially displaceable within the lumen. On the other hand, figure 15 of Goble et al. teach a suture locking plug that has a shaft axially displaceable within the lumen. Thus, it would be obvious to modify the invention of figure 23 to include the teaching of a suture

locking plug that has a shaft axially displaceable within the lumen for the purpose of precise control of suture tension.

Regarding claim 27, Goble et al. as modified that as applied to claim 24, as well as, an anchor body that further includes a suture pulley (141) fixed with respect to the anchor body such that the length of suture may be passed into lumen from the proximal end, looped around the pulley, and passed out of the lumen through the proximal end, as recited in column 11, lines 60-67, column 12, and seen in figure 23.

Regarding claim 28, Goble et al. as modified disclose that as applied to claim 27, as well as, a fixed suture pulley is that formed in a sidewall of the lumen, as recited in column 11, lines 60-67, column 12, and seen in figure 23.

Regarding claim 29, Goble et al. as modified disclose that as applied to claim 28, as well as, an anchor body having a generally tubular body defining the lumen (140, 143, 144) therein, and the fixed suture pulley (141) is defined by a rod (142) disposed transversely around a portion of the body and distal to an opening in the body, as recited in column 11, lines 60-67, column 12, and seen in figure 23.

Regarding claim 30, Goble et al. as modified disclose that as applied to claim 24. Further, a fixed suture pulley that is defined by a bridge between two spaced apertures at the distal end of the body is also within the scope of the invention and it would be

obvious to one with ordinary skill in the art, to have the pulley at the distal end, for the purpose of increasing suture retention.

Regarding claim 31, Goble et al. as modified disclose that as applied to claim 24, as well as, a suture locking plug that interferes with axial movement of the length of suture in the second position by compressing the length of suture against the anchor body, as recited in column 11, lines 60-67, column 12, and seen in figure 23.

Regarding claim 32, Goble et al. disclose a method via a suture having two free ends; providing an anchor body (136) having an open proximal end and a lumen (140, 143, 144), and a pulley (141) fixed with respect to the anchor body; passing the two free ends of the length of suture into the lumen of the anchor body through the open proximal end, looping them around the pulley, and extending the two free ends out of the lumen through the open proximal end; fixing the anchor body with respect to a body cavity; tightening the loop of suture material by pulling on one or both of the two free ends of the length of suture; and fastening the two free ends of the length of suture with respect to the anchor body without knots, as recited in column 11, lines 60-67, column 12, and seen in figure 23. However, Goble et al. do not explicitly recite first a passing a length of suture through soft tissue so that a loop of suture material is embedded in the soft tissue resulting in two free ends. On the other hand, it would be obvious to one with ordinary skill in the art to first pass the suture through soft tissue for the purpose of fastening tissue to bone.

Regarding claim 33, Goble et al. as modified disclose that as applied to claim 32, as well as, soft tissue is a tendon, and a body cavity is formed in a bone, as recited in column 2.

Regarding claim 34, Goble et al. as modified disclose that as applied to claim 33. Further, a tendon that is the rotator cuff tendon, and wherein the bone is the humerus is also within the scope of the invention.

Regarding claim 35, Goble et al. as modified disclose that as applied to claim 32. Further, although shown as a screw, it would be obvious to modify the anchor body to so that fixing the anchor body with respect to the body cavity is via forming the body cavity, passing the anchor body into the body cavity, and radially expanding anchoring structure on the anchor body. The specification for the current application, states that the anchoring body can be anchored in numerous ways and the invention is not limited by the anchoring method. This further applies to claim 36.

Regarding claim 37, Goble et al. as modified disclose that as applied to claim 32, as well as, a suture locking plug movable within the lumen from a first position which does not interfere with axial movement of the two free ends of the length of suture to a second position that compresses the two free ends of the length of suture against the lumen and interferes with axial movement thereof, the step of fastening including

displacing the suture locking plug from the first position to the second position, as recited in column 11, lines 60-67, column 12, and seen in figure 23.

Regarding claim 38, Goble et al. as modified disclose that as applied to claim 37. However, a proximal actuation rod that is coupled to the suture locking plug that extends of out of the lumen from the proximal end of the anchor body, the step of displacing the suture locking plug comprising displacing the actuation rod in a proximal direction with respect to the anchor body has not been explicitly shown in figure 23. On the other hand, alternate embodiments of Goble et al. show this concept. Thus, it would be obvious to one with ordinary skill in the art and within the scope of the invention to modify the invention for the purpose of proper deployment and security.

Allowable Subject Matter

7. Claims 5, 9, 26 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 15, 24, and 32-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26 and 36-40 of copending Application No. 09/867,488. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly more narrow in some aspects while slightly more broad in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US 2003/0149448; US Patent No. 6,656,183; US Patent No. 6,585,730; US Patent No. 6,355,053; US Patent No. 6,146,406; US Patent No. 5,562,689; US Patent No. 5,472,452; and US Patent No. 5,002,550.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

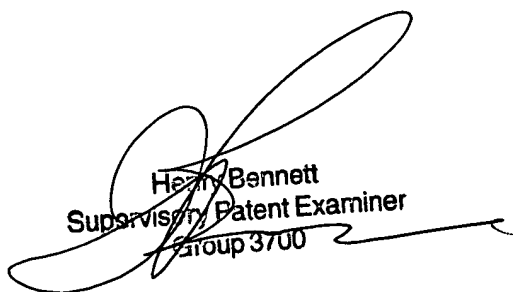
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO


Henry Bennett
Supervisory Patent Examiner
Group 3700